

Therapeutic effects of acupuncture for neurogenic dysphagia—a randomized controlled trial

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and fluid consistencies displayed greater improvement in the experimental group than in the two control groups.

CONCLUSIONS: This study demonstrates that acupuncture may have therapeutic effects and long-term efficacy for neurogenic dysphagia. However, due to an insufficient sample size and the lack of follow-up for control group 2, multi-centre trials employing a larger sample size may be required to draw concrete conclusions.

Abstract

OBJECTIVE: To evaluate the therapeutic effects and long-term efficacy of acupuncture for neurogenic dysphagia.

METHODS: Subjects with neurogenic dysphagia undergoing routine swallowing management were randomized to receive either 20 sessions of true acupuncture (experimental group) or sham acupuncture (control group 1) for approximately one and a half months. A third group (control group 2) comprised of non-randomized subjects with neurogenic dysphagia who received routine care were recruited from separate wards. The outcomes were assessed by the Royal Brisbane Hospital Outcome Measure for Swallowing (RBHOMS), as well as by the consistencies of ingested food and fluid.

RESULTS: A total of 87 subjects (experimental group, $n=20$; control group 1, $n=19$; control group 2, $n=48$) were recruited into the trial. The average RBHOMS score showed a greater improvement in the experimental group and in control group 1 than in control group 2. The average levels of food

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Key words: Randomized controlled trial; Neurogenic dysphagia; Acupuncture

INTRODUCTION

Eating and drinking are the basic pleasures of life. However, in various neurological disorders, dysphagia is a common symptom. This disorder primarily affects the oral and pharyngeal phases^[1,2]. Typically, tongue movements are uncoordinated, propulsion of the tongue base is reduced, the swallowing reflex is delayed, and laryngeal lifting and contraction of the posterior pharyngeal wall is reduced^[2-5]. Neurologic disorders, such as stroke, Parkinson's disease and dementia, can produce difficulty in swallowing and cause undernutrition, or the dysphagia may combine with other complications and lead to death^[5-8]. The effectiveness of swallowing therapies, such as modifying feeding position and learning special skills, for the treatment of dysphagia may not be significant^[9-10]. Thus, acupuncture may be valuable in treating neurogenic dysphagia. The results of our study are presented below. This study was

approved by the appropriate ethics committees and was performed in accordance with the ethical standards laid down in the Declaration of Helsinki. All persons signed their informed consent prior to their inclusion in the study.

METHODS

Subjects

The subjects were patients with neurogenic dysphagia recurrently admitted to the subacute and rehabilitation medical wards of a post-acute hospital in Hong Kong, recruited between March 2009 and April 2010.

Information about the aim and flow of the study was presented to the subjects, who subsequently provided informed written consent prior to study commencement.

Inclusion criteria

Inclusion requirements were as follows: 1) stable medical condition; 2) a diagnosis of neurogenic dysphagia by a physician and referral to a speech therapist for assessment and management; and 3) diagnosis within the preceeding year of one or more of the following: stroke, Parkinson's disease or vascular dementia.

Exclusion criteria

The following individuals were excluded: 1) those with structural oral, pharyngeal or esophageal diseases; 2) those with severe primary diseases of the liver, kidneys, hematopoietic system or endocrine system; 3) those with malignant tumors or infectious diseases; 4) psychotic, unconscious or severely demented patients who are unamenable to acupuncture and those who are unable to follow commands; 5) those with brain stem encephalitis, multiple sclerosis, amyotrophic lateral sclerosis, motor neuron disease, poliomyelitis and postpolio syndrome, Guillain-Barre syndrome, myasthenia gravis or myopathy; 6) those with iatrogenic oral/pharyngeal dysphagia or psychogenic dysphagia; 7) pregnant women and those who were lactating or menstruating; 8) those who refused to participate in this research, refused to undergo acupuncture or who did not want to continue to participate in our study; 9) those with Alzheimer's disease, severe damage of the brain or severe aged-related changes; and 10) those taking warfarin or low-molecular-weight heparin.

Randomization and blinding methods

Subjects with recurrent neurogenic dysphagia undergoing routine swallow management were randomized by block randomization. They received 20 sessions of either true acupuncture (experimental group) or sham acupuncture (control group 1) for about one and a half months. A third group (control group 2) comprised of non-randomized subjects with recurrent neurogenic dysphagia who received routine care were recruited

from separate wards.

Random sequences were written on black paper and sealed in opaque envelopes. The envelopes were kept by an investigator who was not an assessor of the study. The subjects and the investigators who assessed the outcome were blinded to treatment conditions.

Interventions

Swallowing therapies (details below) were given to the subjects in the experimental group, control group 1 and control group 2. Acupuncture treatment was given to the experimental group and control group 1. Course 1 acupuncture treatment (sessions 1 to 10) was performed on consecutive days on subjects after baseline assessment. Course 2 acupuncture treatment (sessions 11 to 20) was performed on alternate days after completion of course 1 treatment. There was a one week rest period, without acupuncture, between course 1 and course 2. Each treatment session was 30 minutes in duration, with the subjects in the supine or sitting position.

Acupuncture procedure

Experimental group: Wangu (GB 12), Fengchi (GB 20) and Yifeng (SJ 17) were each bilaterally punctured with the tip of a 1.5 *cun* filiform needle, pointed toward the Adam's apple, for 0.8 – 1.2 *cun*. The needle retention time was 30 minutes after the de *qi*. Lianquan (CV 23) was punctured obliquely with the tip of the needle pointed towards the radix lingua for 0.8 – 1.2 *cun*. Electro-acupuncture was applied to Wangu (GB 12), Fengchi (GB 20), Yifeng (SJ 17) and Lianquan (CV 23). The waveform was a dense-disperse wave and the frequency was 5 Hz. The intensity was adjusted to the tolerance of the subjects. The post pharyngeal wall and the dorsum of the tongue were punctured and pricked swiftly ten times using a 3 *cun* filiform needle. Cough or gag reflexes were occasionally elicited when puncturing these points. Other optional acupoints were used based on the subject's particular signs and symptoms.

Control group 1: Subjects in this group were given sham acupuncture that did not puncture true acupoints lying on a meridian.

The points punctured were: 1) the point between Sidu (SJ 9) and Quchi (LI 11); 2) the point between Zusanli (ST 36) and Yanglingquan (GB 34); and 3) the point between Xuanzhong (GB 39) and Fuyang (BL 59). A 1 *cun* filiform needle was used to puncture 0.3 – 0.5 *cun* without further manual manipulation and no electroacupuncture was used. These points were punctured bilaterally.

Control group 2: No acupuncture treatment was administered to this group of subjects.

Swallowing therapies

The speech therapist assessed the subject's cognition, communication and oral motor function, to determine

swallowing ability. The management and treatment plans were designed individually for each subject. The treatment included oral motor exercises, different swallowing techniques, positioning and diet modification. These training exercises and strategies were used to strengthen the swallowing muscles, reinforce oral care, and to promote clearance of secretions from the respiratory tract to maintain an unobstructed airway for breathing. All these were performed to reduce the risk of aspiration, choking, suffocation and other complications associated with swallowing difficulties.

The direct strategies involved exercises using food and fluids. The subjects were asked to swallow in accordance with specific instructions, which included; changing feeding position, modifying the consistency, volume and speed of food and fluid intake, performing dry swallows after intake of food and fluid, and increasing the amount of sensory input during swallowing.

In contrast, the indirect strategies involved exercises to

stimulate and strengthen the oral and pharyngeal structures without food and liquid intake. For instance, range-of-motion tongue exercises.

Outcome measures

The Royal Brisbane Hospital Outcome Measure for Swallowing (RBHOMS) was implemented during clinical bedside assessment^[11]. RBHOMS is a validated clinical tool with a 4-stage, 10-point, ordinal scale designed for documenting functional changes in swallowing disability over time and across different etiologies. The four stages are: A, nil by mouth; B, commencing oral intake; C, establishing oral intake; and D, maintaining oral intake. The 10 points are described in Table 1.

Food and fluid consistencies were set according to the current meal textures of the hospital. These were individualized according to the findings from clinical tests.

Table 1 The Royal Brisbane Hospital Outcome Measure for Swallowing

Stage	Level	Description
A	1	Patient aspirates secretions
	2	Difficulty managing secretions but protecting airway
	3	Coping with secretions
B	4	Tolerates small amounts of thickened/thin fluids only
C	5	Commencing /continuing modified diet- supplementation is being provided
	6	Commencing/continuing modified diet - no supplementation provided
	7	Upgrading of modified diet
D	8	Swallowing function at patients' optimal level
	9	Swallowing function at premorbid / preadmission level
	10	Swallowing function at better than premorbid/ preadmission level

Table 2 Food consistencies

Level	Diet	Description
1	Regular	Normal food texture
2	Soft	Normal texture of steamed rice or equivalent & Soft texture of food
3	Minced	Soft texture of steamed rice & minced food
4	Smooth soft	Soft texture of steamed rice + soft texture of food
5	D pureed meat soft rice	Soft texture of steamed rice + pureed texture of food
6	D puree	Pureed food only
7	NGT	Nasogastric tube feeding

Table 3 Fluid consistencies

Level	Fluid
1	Thin fluid (100ml fluid with 0 ml thickener)
2	Slightly thickened fluid (100ml fluid with 10ml thickener)
3	Mildly thickened fluid (100ml fluid with 15ml thickener)
4	Medium thickened fluid (100ml fluid with 20ml thickener)
5	Extra thickened fluid (100ml fluid with 25ml thickener)
6	Nasogastric tube feeding (NGT)

The outcome measures were assessed and documented at baseline, after the completion of acupuncture treatments course 1 (week 2) and course 2 (week 4), as well as three months after the last treatment session (week 18).

Statistical analysis

SPSS 17.0 software was used for statistical analysis. One-way ANOVA, χ^2 test, Kruskal-Wallis test and Wilcoxon Signed Ranks test were performed. $P < 0.05$ (2 sided) was considered statistically significant. The drop-

outs were excluded from analysis.

there was no significant difference in the baseline data between the Chinese and Western medical diagnoses among subjects from the three groups. Therefore, the results are comparable.

RESULTS

As the results presented in Tables 4 to 6 demonstrate,

Table 4 Baseline data and characteristics

	Experimental group	Control group 1	Control group 2
Sample size	20	19	48
Age (year)	74.05 ± 11.057	80.05 ± 9.419	75.38 ± 12.824
Gender			
Male	10 (50.00)	7 (31.82)	26 (54.17)
Female	10 (50.00)	12 (54.55)	22 (45.83)

Note: Data presented as either mean ± SD or n (%), where appropriate. No differences were found between the three groups ($P>0.05$).

Table 5 Western medical diagnoses

	Experimental group	Control group 1	Control group 2
Cerebral infarct < 6 months	16 (80.00)	12 (63.16)	32 (66.67)
Cerebral infarct > 6 months, < 1 year	0 (0.00)	0 (0.00)	5 (10.42)
ICH < 6 months	4 (20.00)	6 (33.33)	3 (6.25)
ICH > 6 months, < 1 year	0 (0.00)	0 (0.00)	2 (4.17)
Vascular dementia	1 (5.00)	3 (16.67)	8 (16.67)
PD	0 (0.00)	0 (0.00)	2 (4.17)

Note: ICH, Intracranial hemorrhage; PD, Parkinson's disease; Data presented as n (%). No differences were found between the three groups ($P>0.05$).

Table 6 Syndrome classification in Chinese medical diagnoses

	Experimental group	Control group 1	Control group 2
Adverse rising of the stomach- <i>qi</i>	2 (10.00)	0 (0.00)	6 (12.50)
Phlegm and dampness stasis	9 (45.00)	7 (36.84)	13 (27.08)
Stomach - <i>yin</i> deficiency	3 (15.00)	3 (15.79)	8 (16.67)
Stomach- <i>qi</i> deficiency	6 (30.00)	9 (47.37)	21 (43.75)

Note: Data presented as n (%). No differences were found between the three groups ($P>0.05$).

Figure 1 shows the average RBHOMS score for each of the three groups at different time points during the trial. At week 4, the improvements in the RBHOMS score were 10.48%, 12.78% and 4.86% for the experimental group, control group 1 and control group 2, respectively. At week 18, the improvements in the RBHOMS score were 40.66% and 35.00% for the experimental group and control group 1, respectively. Statistically significant differences in the RBHOMS scores before and after 2 courses of treatment were found in the experimental group and control group 1 ($P<0.05$).

Figures 2 and 3 display the average food and fluid consistencies for the three groups at different time points during the trial. At week 4, the improvements in the average food consistencies were 24.56%, 8.76% and 3.52% for the experimental group, control group 1 and control group 2, respectively. At week 18, the improvements were 41.58% and 30.56% for the experimental group and control group 1, respectively.

At week 4, the improvements in the average fluid consistencies were 22.22%, 15.57% and 2.12% for the experimental group, control group 1 and control group 2, respectively. At week 18, they were 46.30% and 35.69% for the experimental group and control group

1, respectively.

Statistically significant differences in the food and fluid consistency levels before and after 2 courses of treatment were found for the experimental group and control group 1 ($P<0.05$).

Adverse effects were recorded during the trial. Some of the subjects felt pain (18.44%) during puncturing or mild bleeding (9.53%) from the puncture points. A few cases reported petechia (2.30%) or slight dizziness (1.15%). These adverse reactions were tolerated by the subjects. We did not observe severe adverse reactions during acupuncture, such as infections, fainting or large scale bleeding from the puncture points, in our geriatric patients.

DISCUSSION

In TCM, dysphagia may be categorized into wind stroke (中风), yinfei (暗瘕) or dysphagia-occlusion (噎膈), with symptoms of the mouth, tongue, pharynx and esophagus^[12]. A deficiency of kidney-*yin*, emptying of the sea of marrow, and obstruction of the meridians and collaterals by wind-phlegm and/or blood stasis are possible etiological factors in dysphagia^[13].

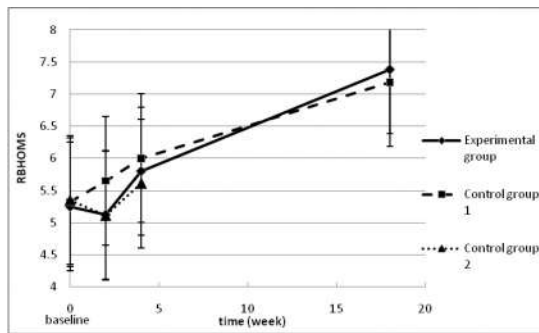


Figure 1 The average RBHOMS scores for the three different groups during the trial.

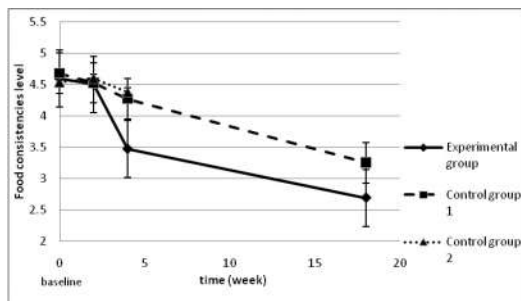


Figure 2 The average food consistencies for the three different groups during the trial.

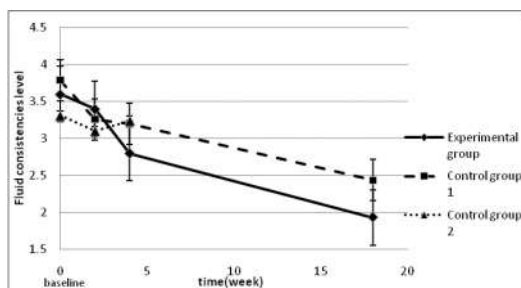


Figure 3 The average fluid consistencies for the three different groups during the trial.

Clinical trials show that formal swallowing therapies do not have any significant effect on the resolution of dysphagia^[9]. Systematic reviews suggest that acupuncture can help resolve neurogenic dysphagia^[14-16]. Herbal medicine, given orally, may not be suitable for subjects with swallowing difficulty. Due to this limitation, acupuncture may be a more appropriate treatment for dysphagic patients. Although there are a number of reports suggesting that acupuncture is beneficial for the treatment of dysphagia, most of these studies are of low methodological quality^[16]. For example, most studies have a small sample size and do not include adequate blinding or controls. In addition, little attention has been paid to the long-term efficacy of acupuncture on dysphagia, and there is no consensus on the selection of acupoints, course of treatment or the outcome measures used to examine the effects of treatment. Considering these limitations, we aimed to evaluate, in this study, the therapeutic effects and long-term effica-

cy of acupuncture on neurogenic dysphagia.

The RBHOMS scores demonstrate that swallowing improved during the course of the trial in all of the groups. From baseline to the end of week 4, the RBHOMS scores in the three groups changed from "Commencing/continuing modified diet—supplementation is being provided" to "Commencing/continuing modified diet—no supplementation provided". Improvements in the RBHOMS score were observed in the experimental group and control group 1 during the follow-up assessment. Their RBHOMS scores exhibited approximately two levels of improvement, from "Upgrading of modified diet" to "Swallowing function at patients' optimal level", as revealed by the follow-up assessment. Thus, after two courses of treatment, subjects were able to ingest their diet orally and maintain an adequate nutritional level without the need for supplementation.

There were improvements in the average food and fluid consistency levels in all three groups during the trial. A greater improvement in the average food and fluid consistency levels was observed in the experimental group. From baseline to the end of week 4, the average food consistency was upgraded from D, pureed eat soft rice, to minced diet in the experimental group, and the fluid consistency was upgraded from 3.5 to 2 teaspoons of thickener.

The enhancements in the average RBHOMS scores and in the average food and fluid consistency levels could be due to several reasons: 1) Natural recuperation from the disease, with swallowing function recovering over time. Most of the subjects in each of the three groups were diagnosed with stroke. Dysphagia could be resolved and swallowing function could be regained within one week to one month, but 8% to 50% of the subjects continued to have swallowing problems after six months^[5,17-19]. While the interval between the onset of the disorder and the start of treatment was less than one month, spontaneous recovery of swallowing was likely to occur during the course of treatment. 2) The percentage improvements in the average RBHOMS scores and food and fluid consistencies in the experimental group and control group 1, which received acupuncture, were higher than in control group 2, which did not receive acupuncture. This suggests that acupuncture may be beneficial, alongside routine swallow management, for the treatment of dysphagia. 3) The incidence of neurogenic dysphagia was higher in the elderly^[5]. This is because the incidence of neurologic diseases, such as stroke and dementia, increases with age, and these diseases are strongly associated with impaired swallowing^[20]. The mean age of subjects in the three different groups was over 75. They were likely to have swallowing problems caused by age-related changes. It is difficult to differentiate the presence of dysphagia from disease or the effects of normal aging on swallowing. It may hinder the efficacy of treatment. 4) The

small sample size is associated with a large type II error, and thus, any result could occur by chance. Due to the small sample size, the efficacy of acupuncture on improving swallowing function and on the improvement in food and fluid consistencies could not be demonstrated with statistical significance.

According to ancient Chinese medical texts, such as the Compendium of Acupuncture and Moxibustion (《针灸大成》) and Golden Prescriptions (《千金方》), Wangu (GB 12), Fengchi (GB 20), Yifeng (SJ 17) and Lianquan (CV 23) are described as being able to treat "weakness of the lower limbs, throat impediment, dental caries, mouth and eye deviation", "aphasia and difficulty in swallowing due to wind stroke" and "stiffness of the mouth and tongue, difficulty in swallowing".

Seki *et al*^[21] showed that acupuncture improves swallowing function and reduces the incidence of aspiration pneumonia in dysphagic stroke patients by restoring the swallowing reflex. They suggest that acupuncture may be able to modulate subcortical gray structures and alter regional brain activity, thereby regulating the swallowing reflex^[21]. However, the mechanisms of action of acupuncture for neurogenic dysphagia are still unclear^[15].

In conclusion, in this study, we demonstrate that acupuncture might have therapeutic effects and long-term efficacy for treating neurogenic dysphagia. However, due to an insufficient sample size and the lack of follow-up for control group 2, multi-centre trials conducted with a sufficient sample size may be required to draw concrete conclusions regarding the use of acupuncture therapy for neurogenic dysphagia.

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